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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,506	10/17/2001	Gregory R. Chiklis	19383-014	6911
7590	10/20/2005		EXAMINER	
Ranjana Kadle Hodgson Russ LLP One M & T Plaza Suite 2000 Buffalo, NY 14203-2391			WANG, LOUISE Z	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/981,506	Applicant(s) CHIKLIS ET AL.	
	Examiner Louise Wang	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-63,65,66,68 and 69 is/are pending in the application.
 4a) Of the above claim(s) 5-11,16-48,53-59,62,63,65,66,68 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-4,12-15,49-52,60 and 61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 2-9, 12-17, 49-57, and 60-63, in the reply filed on 29 August 2005 is acknowledged. The traversal is on the ground that the Groups I, III, and V are not distinct from each other. This is not found persuasive because Groups I, III, and V are related to as product, process of making and process of use, which are distinct because Group I can be used for a materially different process such as therapeutics to treat diseases. This has been known in the art, see Balachandran *et al.* (IUBMB Life, 2000). Therefore, the restriction among Groups I, III, and V is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 5-11, 16-48, 53-59, 62, 63, 65, 66, 68, and 69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 August 2005.

Claims 2-4, 12-15, 49-52, 60, and 61 are pending and examined.

The claims are read to the extent of the elected species, i.e., formaldehyde and HIV.

Information Disclosure Statement

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The information disclosure statement (IDS) submitted on 15 July 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 12-14, 49-51, and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a purified microorganism comprising surface proteins and substantially intact nuclear components, wherein one or more surface proteins have been irreversibly modified by covalent attachment of formaldehyde to render the microorganism nonpathogenic; a composition comprising the microorganism; and a kit comprising the composition. The phrases "microorganism" and "a compound" in claim 2 encompass an unlimited number of species known in the art. The limitation "surface proteins" is not defined by any names or structures and hence the scope of the claims extends unlimitedly to any protein that comes into contact with formaldehyde. Since no conditions of "covalent attachment" are included in the claims, they are

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understood as extending to any known prior art HIV cell or tissue fixative solution containing formaldehyde. The limitations "the compound" comprising "a single reactive functional group" in claims 3 and 51 as well as "liquid matrix...suitable for lyophilization" in claims 12 and 13 extend to any organic compound or formulation known in the prior art such as Bouin's solution or formalin. The phrase "virus" in claims 14 and 60 does not require that the virus possess any particular biological activity or other distinguishing feature. Thus, claims 14 and 60 are drawn to all viruses known to one skilled in the art.

In order to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. In this case, there is not even identification of any particular surface protein, virus and compound. The specification only provides the example of HIV soaked in formaldehyde and assay for p24. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, Claims 2, 3, 12-14, 49-51, and 60 do not meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 12-15, 49-52, and 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison *et al.* (1996). These claims are drawn to a purified nonpathogenic HIV comprising surface proteins irreversibly modified by covalent attachment of formaldehyde and substantially intact nuclear components; a composition comprising the HIV and a liquid matrix; and a kit comprising the composition.

Davison *et al.* teaches the claimed noninfectious HIV, with quantifiable DNA for PCR, in brain tissue fixed with formalin, a formaldehyde solution (see entire document).

Thus, claims 2-4, 12-15, 49-52, and 60-61 are anticipated by Davison *et al.*

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Wang, Ph.D.
Patent Examiner
12 October 2005



JEFFREY STUCKER
PRIMARY EXAMINER